# COURAGE Chronicle

Courage Chronicle April 1999

## PENTABLET UPDATE

During extensive pre-trial data testing of the Epimetrics Intake program at Emory Center for Outcomes Research, several Pentablet problems have been identified.

This means that the software application on each machine must be uninstalled and the new version of the application installed prior to data entry on the computer. Disks with the new version of the application and specific instructions for uninstalling and reinstalling will be shipped to each site. Kate Hanson will be sending another email/fax to let you know when the software has been sent.

**If you have encountered any problems with the Pentablet, please contact Kate as soon as possible so that she can have all of the programming changes made at the same time.**

Kate's E-mail: kate@hp3.eushc.org Phone: 404-727-9235

We will be holding a series of conference calls so you can dial in to our group help sessions for assistance with this process, as well as the installation of the revised Scheduling System disk. Times and dates of these conference calls will be published in the next Courage newsletter.

## REGULATORY ISSUES

A Memorandum was sent to all coordinators dated April 8, 1999 emphasizing that any materials presented to patients including advertising, American Heart Association pamphlets, and the PACE material needs to be submitted to your IRB for approval before using them. We suggest that you do the following:

- Make photocopies of the American Heart Association pamphlets that you will be receiving from West Haven in the near future.
- Copy the PACE forms on Diet, Exercise, and Smoking that you will receive from the West Haven coordinating site in the near future. You already have these forms from the kick off meeting you attended but we will send copies of the patient forms for your convenience.
- Make copies of any advertising material you will use.
- Submit all of the above material to your IRB. Once approval is obtained, send the IRB approval letter to both the West Haven coordinating site and fax a copy to Karen Potter, RN, Project Coordinator at fax # (315) 477-4579 along with copies of what was submitted to the IRB for approval.

If you have any question regarding this matter, contact Karen Potter, RN, Study Coordinator, V.A. Medical Center, Syracuse, NY at phone # (315) 476-7461 Ext. 2806 or toll free at 1-800-215-7330 or e-mail to karen.potter@med.va.gov

## NOTES FROM WEST HAVEN

Letters of agreement (LOA's) between the Department of Veterans Affairs and the enrolling U.S. (non VA) and Canadian sites, were sent out on March 23rd. Funds will be distributed to each site when the signed LOA *and* unconditional IRB approval documents have been forwarded to West Haven CSPCC.

***A reminder from the Pharmacy Coordinating Center regarding the approval process for the study:***

All sites must have an *unconditional* approval dated after February 9, 1999 (date of amended protocol which should have gone back to your governing bodies).

**VA Sites** must have either a copy of the signed minutes from the R & D committee or, a copy of a letter or memo from the Chairman of the R & D committee showing unconditional approval, plus a copy of the signed minutes from the Subcommittee on Human Studies/IRB or, a copy of a letter or memo from the Chairman showing unconditional approval, or VA form 10-1223.

**Non VA Sites** must have either a signed copy of the minutes from the IRB committee meeting (or equivalent for the Canadian sites) or a copy of a letter or memo from the Chairman of the IRB committee (or equivalent for Canadian sites), showing unconditional approval.

- Remember that all signatures must be signed over the chairman's *OFFICIAL SIGNATURE BLOCK*.
- All signatures must be from the Chairman of the respective committee or designee showing approval.
- Any satellite sites are subject to the same requirements and your 1572 must reflect that research will be conducted at a satellite site.
- CV's are required for all PI's *and* sub-investigators.

Send the above items to Nancy Morgan or Jolene Day in Albuquerque. All sites must also send a copy of their IRB approval letter to Dr. Pam Hartigan in West Haven, CT.


## QUESTION/ANSWER FORUM

Q. When are we going to start enrolling patients?

A. We have encountered unanticipated delays in coordinating this unprecedented multi-faceted clinical trial and are working diligently to resolve every issue before we start enrolling patients. Contracts are in the process of being finalized and we anticipate approval to start enrolling patients within the first few weeks of May. We will notify everyone of the date as soon as we know.

Q. What do I do if my phone number or fax number or e-mail address changes?

A. Notify Liz Petrokaitis at the West Haven Data Coordinating Center at 1-888-803-5560 as well as your Project Coordinator.

Q. Are we going to be monitored?

A. Site visits will be random and will probably not occur until about six months after we start enrolling patients. However, we will be conducting teleconference calls and will notify you of these times.

## CANADIAN CORNER

CLARIFICATION: All Canadian sites recently received a letter from Dr. Teo dated April 13, 1999 to clarify the issue of funding by the MRC. Please follow his instructions on how to complete the HPB Form "HPB 3005 (2-90) and FDA Form 1572 and disregard the instructions you recently received in a letter from Nancy Morgan at the Albuquerque Pharmacy Coordinating Center. Dr. Teo's instructions are more accurate. Any questions, call Karen Potter, Project Coordinator.

We intend to send this newsletter every month in an attempt to inform you of issues relating to the study. We hope you will think of this publication as your newsletter and that you will send us your ideas, questions and comments.

We want to hear from you!

Send your suggestions to:
Karen Potter, RN, BSN
Syracuse VA Medical Center
Cardiovascular Clinical Trials RM. 802
800 Irving Avenue
Syracuse, NY 13210-2799
Phone: 315-476-7461 Ext. 2806 or 1-800-215-7330
Fax: 315-477-4579
E-mail: karen.potter@med.va.gov